IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Serial No.:	10/748,524
Applicant:	Richard E. Parizek *et al.*
Confirmation No.:	8568
Filed:	December 29, 2003
Group Art Unit:	1645
Examiner:	Jana A. Hines
For:	A multicomponent vaccine containing clostridial and non-clostridial organisms in a low dose
Attorney Docket:	1995.184 US D1

April 18, 2008

LETTER

Box: AF
Honorable Commissioner of Patents
P.O. Box 1450
Alexandria, VA 22313

Sir:

Submitted herewith is a "Letter" filed July 11, 2003, in parent application U.S. Serial Number 08/412,676, along with attachments submitted with that Letter. It is respectfully requested that the Letter and its attachments be entered into the record for this divisional application.

The purpose for this submission is to assure that evidence submitted in the parent application be considered in the present case. That submission set forth that, in an accompanying Declaration by Dr. Karen K. Brown, market share results illustrating the effect of the introduction of a 2 ml 7 way clostridial combination vaccine. Dr. Brown reported that in September of 1995 the vaccine based on that invention, which was a seven way clostridial combination with a H.somnus, was introduced at a price six times higher than conventional vaccines having the same antigens but in a 5 ml dose form. Dr.

Brown provided a graphical representation showing the increased in market share of the 2 ml product compared with three significant competing products having the same antigens but sold in 5 ml dose sizes. In the Declaration Dr. Brown reports that on introduction the 2 ml product captured 15% of the market share. It increased to a 35% market share in 1996, the next year, and then to a 40% market share to the date of the Declaration in December of 1997. She also reported that the market share in 1997 was limited due to production inability to meet the market demand and that, specifically, is back orders, orders that had already been placed, could have been filled the product would have achieved a 60% market share in 1997. This, in little more than two years, even though the product sold for six times the price of competitive products having the same antigens. These results illustrate the unobviousness of introducing a clostridial combination vaccine in a 2 ml dose format.

Also submitted with the Letter of July 11, 2003 are publications illustrating a long felt need to reduce injection site lesions and the consequent meat spoilage, and the enthusiastic acceptance in the market of a 2 ml clostridial combination vaccine.

It is respectively submitted that this evidence further obviates a conclusion of obviousness for Applicants' 2 ml dose multicomponent clostridial combination vaccine.

Respectfully submitted,

William M. Blackstone, PTO Reg. 29,772
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WMB:dap

Enclosures

IN THE UNITED STATE PATENT AND TRADEMARK OFFICE

In re the application of: Box: AF

PARIZEK ET AL.

Serial Number: 08/412,676 Group Art Unit: 1645

Filed: March 29, 1995 Examiner: J. Hines

For: A MULTICOMPONENT VACCINE CONTAINING CLOSTRIDIAL AND NON-CLOSTRIDIAL ORGANISMS IN A LOW DOSE

Letter

Assistant Commissioner for Patents
Washington, D.C.

July 11, 2003

Dear Sir,

Prior to considering the present application, it is respectfully requested that the Examiner review the documents and publications submitted herewith along with the remarks that follow.

All of the publications were submitted with the IDS filed July 14, 1995. In addition, applicants again refer to the Declaration by Dr. Karen K. Brown. That Declaration, although previously on record, was submitted a second time with the response filed February 14, 2003. When originally submitted the Declaration contained a graphical representation of market share as an attachment. By unintentional error this attachment was not included with the Brown Declaration on its second submission. For the Examiner's convenience, copies of all the publications

mentioned below as well as the Brown Declaration with the graphical representation of market share are again submitted herewith.

In the Brown Declaration it is reported that in September of 1995 a vaccine based on the present invention having the product name VISION 7 SOMNUS was introduced at a price six times higher than conventional vaccines having the same antigens ($0.65/dose vs. $0.07 - $0.10/dose) but was extremely successful. Dr. Brown describes the attached graph representing increase in market share of the VISION 7 SOMNUS product compared with three significant competing products containing seven clostridial components combined with *H. somnus* and the market share of 3-4 "sales - volume" products categorized as "OTHER." Dr. Brown reports that all products other than VISION 7 SOMNUS are in a 5.0 mL dose size. It is reported that on introduction in September of 1995 the 2.0 mL VISION 7 SOMNUS captured 15% of the market share. This increased to a 35% market share in 1996, and then to a 40% market share to the date of the Declaration in 1997. Dr. Brown also reported that the market share of VISION 7 SOMNUS in 1997 was limited due to back orders, and their inability to meet the market demand. She reported specifically that if the back orders, orders

that had already been placed, could have been filled VISION 7 SOMNUS would have a 60% market share in 1997.

It is respectfully submitted that the acquisition of market share from zero at the time of introduction in September of 1995 to the 60% market share demand little more than two years later, even though the product sold for more than six times the price of competitive products having the same antigens, is a clear and conclusive illustration of commercial success evidencing that the invention, a 2 mL dose in place of the then available 5 mL dose, met a long-felt and unfilled need.

Regarding the Declaration of Dr. Brown, the Examiner commented in the Advisory Action: "The Declaration is drawn to a long felt need of the claimed vaccine. However establishing long-felt need requires objective evidence that an art recognized problem existed in the art for a long period of time without solution. It appears that the solution was known using low dose vaccines and others in the field were working on such, as evidenced by the instant references which teach using multi-component vaccines dosed at 2 mL. The failure to solve a long-felt need may be due to factors such as a lack of interest or a lack of appreciation of an invention's potential or marketability rather than want of technical know-how."

"Lack of interest" is precluded by the recognized need for a clostridial combination that did not create injection site lesions. "Lack of appreciation of [the] invention's potential" is precluded by the recognition that low dose (2 mL) clostridial vaccines reduced or eliminated injection site lesions. Both are evidenced in the beef industry publications discussed below.

The combination vaccine VISION 7 SOMNUS, the vaccine according to the present invention, taking away market share at the rate of 15% in the first three months, 35% in the first 15 months and, filling existing backorders, 60% in the first twenty-seven months, despite a six fold price differential, fully meets the requirement of the objective evidence that an art recognized problem existed that the invention met. Although 2 mL clostridial vaccines had been introduced earlier, and had taken over the market in response to a long felt need evidenced by the publications provided herewith, the problem remained that no low dose clostridial/*H. somnus* combination vaccine was available. Despite the greater than six fold increase in price, the demand quickly exceeded the ability to produce VISION 7 SOMNUS on its introduction.

The recognition of the desirability of a low dose combination vaccine for clostridials is illustrated in the

marketing literature for Boehringer Ingelheim Animal Health, Inc.'s clostridial vaccines, with which a 1994 Spring Special marketing effort was advertised. Under "CLOSTRIDIALS," their "NEW" Alpha-7™ clostridial vaccine, which solely contains clostridial antigens, is offered in a 2 mL dose. However, their *H. somnus* clostridial combination BAR-VAC®-7/SOMNUS is only offered in a 5 mL dose. This, even though their IBR-PI_3/BAR SOMNUS 2 P™ combination is offered in a 2 mL dose and other combinations, such as SOMATO-STAPH®/LEPTO-5, a 5-way Lepto/STAPH combination, is offered in a 2 mL dose. Even the BAR SOMNUS/2-P™ H.somnus/P.haemolytica combination was offered in a 2 mL dose. Had a 2 mL clostridial/H.somnus combination vaccine been available, it would have been offered as well.

Small dose vaccines were desirable, and this was recognized in the art. This is illustrated, in addition to the present invention's dramatic commercial success, by the competitors offering 2 mL doses whenever possible. Moreover, the fact that this was of particular concern for multi-valent clostridial vaccines is illustrated in the industry literature. After the introduction of the VISION multivalent clostridial vaccine in 1992, no 5 mL multivalent clostridial vaccine would be used if it could

be avoided. Copies of particular articles are again provided for the Examiner's convenience.

In BEEF TODAY, March, 1991, pages 18 & 19, Effertz reports on the loss of meat due to injection-site lesions. In the second paragraph, it is stated, "Today, 12 percent to 15 percent of beef primals have some type of injection-site lesion that must be trimmed away. Retailers and steak cutters are angry. Some chains have threatened to boycott top sirloins from certain regions of the country. It is all that others can do to keep their employees from making a media issue of the problem. They say their concerns are twofold: the safety and wholesomeness of the beef first, and the economic loss associated with product and manpower waste second." In the third column on page 19 it is reported, "Many feedlot managers have opted to reduce their use of 7-way clostridial bacteriums. [These are solely clostridial and not clostridial plus other antigen combination vaccines] 'We haven't been boostering with them for some time.' Sears [feedlot consultant] says. 'Some of our yards don't give any clostridials on heavier incoming cattle. Frankly, we had some difficulty showing an economic benefit for the product on yearling cattle.' Because 7-way is a relatively cheap vaccine, it found routine use in many feedlots, especially late in the

feeding period. Then it was thought to reduce overeating and sudden death cases. 'We used to reason that since it can't hurt and might help, why not use it,' Sears says. 'But I think the potential for bill backs and damage to beef's image should make feeders think twice'." The conclusion in 1991 was to use 7-way clostridials [which were then 5 mL doses] sparingly and sub-Q use only. The NCA (National Cattleman's Association) Task Force reported "All the companies that make 7-way clostridial are in the process of changing labels to request sub-Q use only. Most are investigating other sites and methods of administration for injectable intramusculars. And genetically engineered products promise vaccines with fewer contaminants and possibly irritating adjuvants." (Second to last paragraph on page 19).

In 1992, a 2 mL dose 7-way VISION™ multivalent clostridial vaccine was introduced. As reported by Ditmer in CALF NEWS CATTLE FEEDER, September 1992, pages 42, 43, and 49, referring to the 2 mL clostridial VISION vaccine, it is stated, "To underline the gravity of the injection site problem, as well as the importance of the availability of the new vaccine to combat it, a who's who in beef quality assurance spoke at the news conference. NCA Beef Quality Assurance Task Force members who spoke included,

Jack Algeo, CAL POLY,... Mike Bowles, chairman, ... James Furman DVM, ... Bob Bohlender DVM, and Wes Bonner DVM, Veribest CATTLE FEEDERS, ... Gary Smith, PHD, Colorado State University and National Beef Quality Audit Chairman also spoke." (Paragraph bridging columns 1 & 2 on page 42). Furman reported at length with regard to problems using 7-way vaccines and bill backs from packers due to injection site lesions. To ensure complete eradication of the blemishes packers were taking in excess of 2 pounds at most every injection site and billing back the suppliers for the monetary loss. He reported, "[w]ell, needless to say, this made an awful big impression on me,' Furman said. And from that time on we have not used any 7-way clostridial vaccine on cattle that are under 150 days from slaughter." He then reported that he did not have any problems with the reduced 2 mL dose. The article also describes that the new 2 mL product was not merely a reduced volume but a newly formulated vaccine.

FEED STUFFS, August 24, 1992, Rod Smith reported that the new VISION 2 mL vaccine allowed cattle feeders to vaccinate against clostridial problems while eliminating or reducing significantly "knots" and lesions and improving overall quality. Reporting on the NCA mid-year meeting in

Denver, again the benefit of a 7-way clostridial that would not result in damage to the meat or hide was reported.

The problem with injection site blemishes is also discussed in BEEF TODAY, September 1992. Again, reporting on the NCA Task Force, which first urged feeders and producers to give all clostridial injections sub-Q rather than intramuscularly to reduce tissue damage and the concomitant waste. In addition to reporting the Task Force availability to counter buyers' objections to surface blemishes that are not defects to salable products, the publication reported on the introduction of the 2 mL 7-way clostridial vaccine. "Proving that the animal health industry can respond in record time when challenged to do so. Miles Agricultural Division recently released a less reactive 2-mL clostridial vaccine available in 4-, 7-, and 8-way combinations. (The customary dose for a clostridial is 5 mL.)"

All of the problems described for 5 mL 7-way clostridial vaccines would naturally be found with 5 mL clostridials combined with other antigens.

Five mL multivalent clostridial vaccines were a problem well recognized in the industry. As a result, a 2 mL vaccine was developed, and was welcomed by the industry

in 1992. This was solely a clostridial vaccine and not a combination with other antigens, such as H. somnus. Although vaccine producers quickly offered multivalent clostridial vaccines in 2 mL format after the introduction of VISION, other clostridial combination vaccines remained in the 5 mL format, even though H. somnus combinations with other multivalent bacteriums were available (e.g., Boehringer Ingelheim's BAR SOMNUS/LEPTO-5™ 2 mL H. somnus and 5-way lepto). H. somnus combinations, as illustrated by the Boehringer Ingelheim products, are found in both 2 mL and 5 mL formats depending on the antigens. If a 2 mL clostridial/H.somnus combination vaccine was thought to be possible it would have been offered.

Given the well-documented need at the time the present invention was made for all multivalent clostridial vaccines to be in a low dose format, it may be concluded that it would be obvious to try to formulate such a combination vaccine. Still, as evidenced by the literature, the clostridial/H. somnus combinations remained in the 5 mL format. It was not, however, until applicants succeeded in formulating the presently claimed multivalent clostridial H. somnus combination in a low dose format that still provided protection that such a vaccine was successfully prepared. When introduced, finally, despite costing six

times the price of competitive vaccines it quickly dominated the market in a very cost conscious industry, as illustrated by the results reported in the Brown et al Declaration. The reduction in meat spoilage justified the expense.

In view of the long felt need evidenced by the publications and the commercial success reported by Dr. Brown, it is submitted that the present claims define a patentable invention. Favorable action is solicited.

Respectfully submitted,

4/29/05

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per Wm. Blackstone

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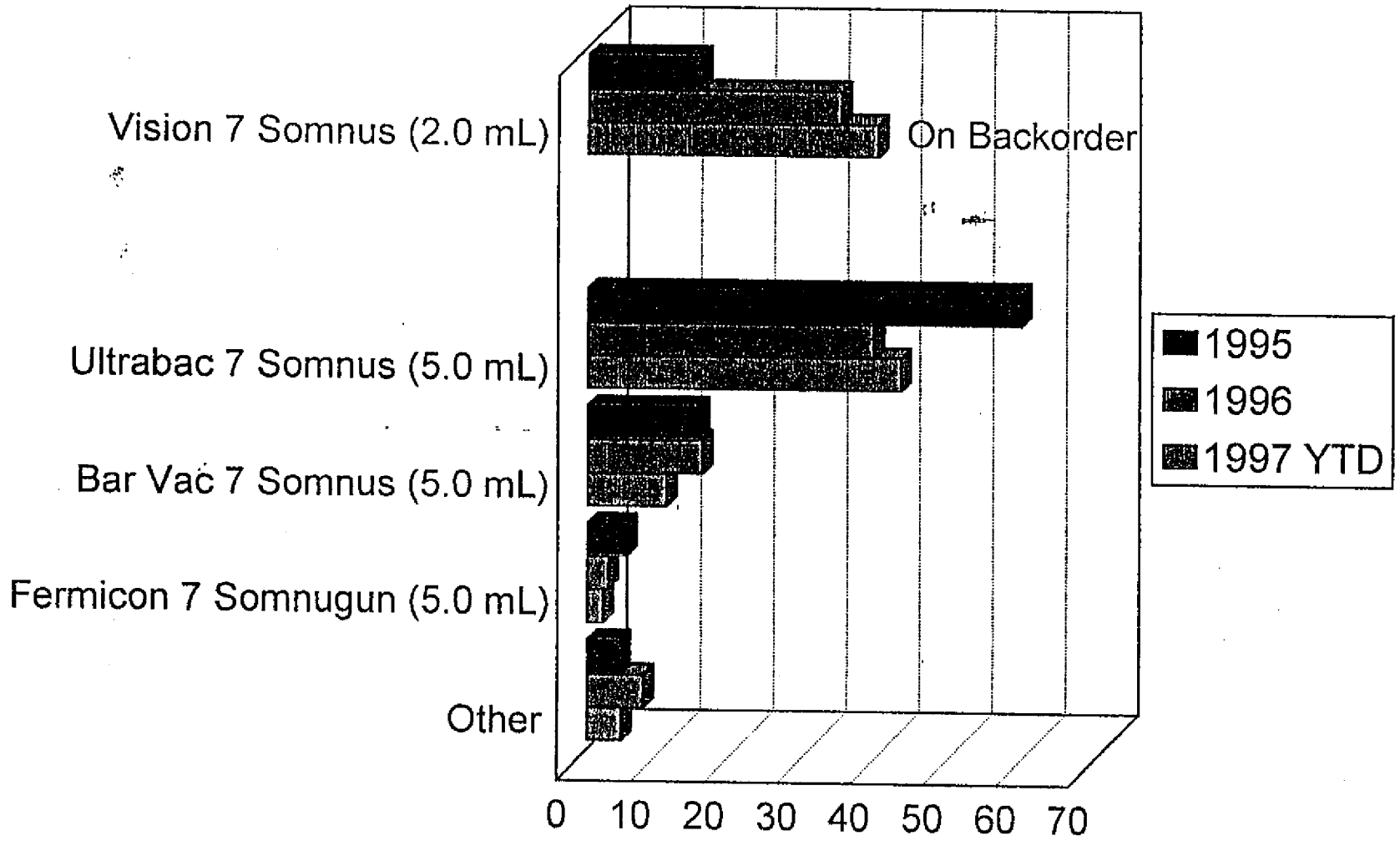
Increase In Market Share of Vision 7 Somnus (2.0 mL) Since Introduction in 1995



Taken from IMS America

PATENT APPLICATION
Mo-4249
MD-94-86

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICATION OF	)	
	)	
RICHARD E. PARIZEK ET AL	)	
	)	
SERIAL NUMBER: 08/412,676	)	
	)	
FILED: MARCH 29, 1995	)	EXAMINER: H. SIDEBERRY
	)	
TITLE: A MULTICOMPONENT VACCINE CONTAINING CLOSTRIDIAL AND NON-CLOSTRIDIAL ORGANISMS IN A LOW DOSE	)	

DECLARATION

Assistant Commissioner for Patents
Washington, D.C. 20231
Sir:

Now comes the Declarant, Dr. Karen K. Brown, as an expert in vaccinology associated with the subject application and declares as follows:

That she has received a Bachelor of Science Degree in Biology and Chemistry and a Ph.D. in Microbiology/Biochemistry.

That she has been employed by Bayer Corporation (formerly known in a chronologically descending order as Miles Inc., Mobay Corporation and Cutter Laboratories) from the year 1972 to date in various research, development and business programs relating to veterinary vaccines, and that from 1977 to 1994 she was directly involved in the research and development of Clostridial vaccines. That since 1994, she has been directly involved in licensing new technologies, as Manager of Licensing and Patent Coordination, wherein such involvement provided knowledge of the areas of technology being researched and developed by universities and competitors, including the area of clostridial vaccines.

That during the prosecution of this application she has become familiar with prior art, cited by the Examiner and discussed hereunder, which were brought to her attention by the attorney of record.

That she is more specifically aware of development, usage and properties of combination of clostridials and non-clostridial vaccines.

That upon review of the prior art, and upon information and belief, she declares that the prior art including the cited references: Siefert et al, Prevention of Anaerobic Infections Of Ruminants In Madagascar By Means of Intradermal Application Of Ultrafiltered Toxoids Prepared From Locality-Specific Clostridia, and Baharsefat et al, Active Immunization of Cattle By Hemorrhagic Antiseptisemic Combination Vaccine (Pasteurellosis) And Symptomatic Anthrax (Quarter Noirs, Black District) In Iran, do not teach or suggest the claimed invention relating to the low dose volume vaccine incorporating clostridial organisms and at least one non-clostridial organism as presently recited by the claims of the subject application. That the Siefert discloses a clostridial organism combined with Bacillus anthraxis and saponin adjuvant and administered intracutaneously (intradermally) as a 2.0 mL dose. That Baharsefat describes a vaccine containing diphtheria combined with Clostridium tetani and Pasteurella spp combined with Bacillus anthracis. That these publications do not teach or suggest the invention of the subject application distinctly relating to a low dose volume vaccine of 3 mL or less containing more than one clostridial organism and at least one non-clostridial organism which is nevertheless safe (non-reactive).

That, as further shown hereunder, the commercial success of the product embodying this invention indicates that the present invention is unobvious. For a period of about five (5) years, in the highly competitive field of the beef industry, there was a long-felt need to reduce the condemnation of meat by slaughter houses and retailers due to blemishes resulting from the use of clostridial vaccines. Scientific and lay articles since 1991 discussed blemishes or injection site lesions as a matter of significant concern for the beef industry and one which could not be solved with current vaccines/technologies. The injection site lesions had to be cut out of the meat and discarded causing significant monetary losses to retailers, beef

packers and feedlots. It was estimated that 12-15% of prime beef cuts had some type of injection site lesions that must be trimmed away (Effertz, Beef Today, March 1991). This article specifically attributes the main cause of the injection site lesions to multicomponent (7-way) clostridial vaccines. The beef industry made multiple pleas to the veterinary vaccine industry to solve this problem. No solution to the problem had been found prior to the introduction of vaccines based on the subject invention (September of 1995).

That at the time of filing of the subject application in March of 1995, there was no other multicomponent vaccine for cattle comprising a safe (non-reactive) and immunogenically effective combination of a protective antigen component from more than one clostridial organism, a protective antigen component from a non-clostridial organism, further containing adjuvants, wherein the vaccine is in a low dose volume of 3.0 mL or less.

That the introduction in September of 1995 of a vaccine based on the subject invention under the product name VISION 7 SOMNUS by the subject assignee, Bayer Corporation, at a price six times higher than conventional vaccines of a similar composition ($0.65/dose vs. $0.07-$0.10/dose) was extremely successful. Attached hereto is a graph representing the increase in market share of the VISION 7 SOMNUS product since its introduction in 1995. The attached graph compares the market shares of the VISION 7 SOMNUS product with the market share of three significant products containing 7 clostridial components combined with H. somnus, and the market share of 3-4 low sales-volume products categorized in the graph as "OTHER" . All products other than VISION 7 SOMNUS are in a dose volume of 5.0 mL. It is clear from the graph that the VISION 7 SOMNUS made according to the subject invention is increasingly capturing market share, going from a 15% market share in 1995 to a 35% market share in 1996 and to a 40% market share to date in 1997. The demand for the product has resulted in a backorder because the assignee did not anticipate the market demand. Apparently, with filling of the backorders, VISION 7 SOMNUS would have a 60% market share year to date 1997. From the foregoing, it is clear that the subject invention has resulted in commercial success.

That the commercial success enjoyed is due to the attributes of the product, namely safety, manifesting in lack of lesions in the meat (non-reactivity) and efficacy of the product, since the promotion of the product was not inordinate. In essence, the promotion of the product was done in essentially the same manner as the art-related products of the assignee. The success of the product is mainly due to its attributes, principally the inventive concept of incorporating the clostridial and non-clostridial organisms in a low dose volume vaccine. This inventive concept has satisfied the long-felt but unmet need of at least 5 years and has helped reduce the economic loss to the beef industry resulting from the condemnation of meat by slaughter houses and retailers due to blemishes associated with prior art, high dose volume clostridial vaccines.

That the commercial success enjoyed by VISON 7 SOMNUS is an indication of the unobviousness of the underlying invention claimed in the subject application.

The Declarant further states that all statements made herein of her own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both under Section 1001 of Title 18 of the United States Code and that such willful false statements and may jeopardize the validity of pending Application Serial Number 08/412,676 filed on March 29, 1995 or any patent issuing thereon.

The Declarant sayeth not.

Signed at Merriam, Kansas, this 8th day of December, 1997.

Dr. Karen K. Brown

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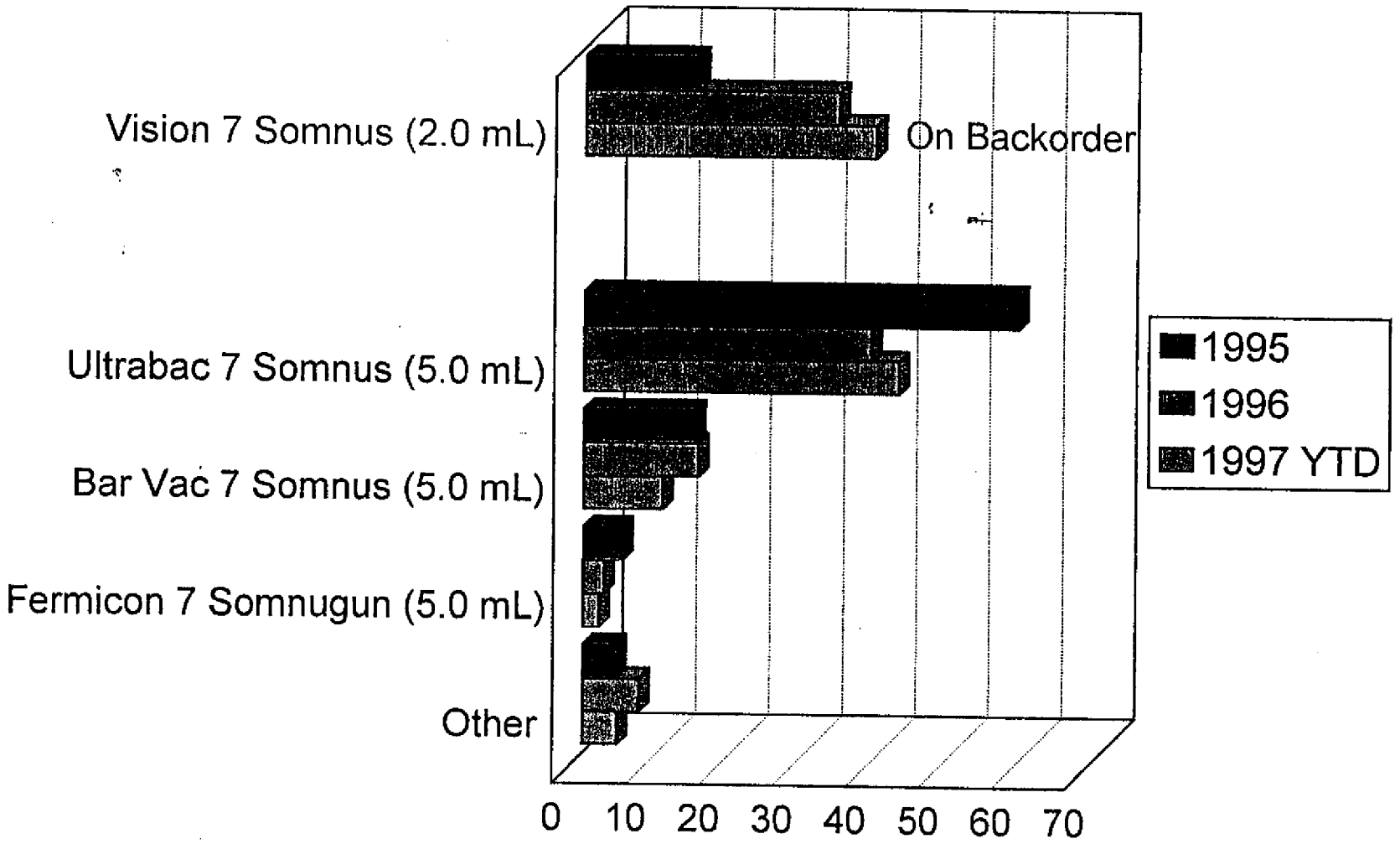
Increase In Market Share of Vision 7 Somnus (2.0 mL) Since Introduction in 1995



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Rec'd 2-4-4 To: Rick Kennedy
copy Dennis Shields

Phil Young
3434 Dallas Rd.
Rockford, IL 6110

Boehringer Ingelheim Animal Health, Inc.
Distributor Policy and Terms

Orders and Correspondence
All correspondence pertaining to billing and accounts receivable should be directed to the Manage Accounts, 2621 North Belt Highway, St. Joseph, Missouri 64506-2002

Shipment to a Distributor is subject to credit approval and will be invoiced at prices prevailing at time the order is shipped. Customers are encouraged to place minimum orders of $2,500 or more.

Standard Terms
Purchases are due and payable net 30 days from date of invoice.

Shipment and Routing
Shipping charges are prepaid on orders of $1,000 or more except on certain F.O.B. items which are indicated. Distributors will be sold in shipper case lots only as defined in the price catalog. Shippin charges for F.O.B. items are prepaid on orders of $1,500 or more. All purchases may be included to qualify for the $1,500 minimum. On orders where we pay transportation charges, we reserve the privilege of shipping via carrier of our choice.

Drop Shipment Policy — Orders that are shipped prepaid to a Distributor's customer must be $ minimum, shipping in case lots only and orders must be placed by the Distributor. Drop shipments will be considered as a separate order.

Special Handling or Routing — When special handling or routing is requested by the Distribut the incremental handling and transportation costs will be charged to the Distributor. The title of al goods sold shall pass to the purchaser upon delivery of goods to the carrier. Pick-up orders at servic centers of less than $250 will be charged a $25 service charge per order.

Damage in Transit
If merchandise arrives in a visible damaged condition, packages damaged should be refused with instructions to the delivering carrier that such merchandise be returned to the shipper for salvage and claim. We are not responsible for losses which may occur in the transportation of merchandise. The transportation company acts as the agent for the Distributor, and we must refer you to them fo reparation in case of loss after you sign receipt of delivery. Boehringer Ingelheim cannot be respon- sible for collecting claims from the carrier, but, when requested, will be of any assistance possible t the Distributor.

Policy on Return Privileges
Boehringer Ingelheim dated products are returnable for credit against future purchases provided they are returned within 120 days after expiration. Approved returns will receive a credit of 100% o the list prices in effect at time less a 10% handling charge and will be limited to an annual ceiling o 2% of the Distributor's previous year of receipt purchases. Approved returns in excess of the 2% ceiling will be credited at 50% of the list price.

ALL AUTHORIZED PRODUCT RETURNS — please ship to:
RETURN GOODS DEPARTMENT
2621 North Belt Highway, St. Joseph, Missouri 64506-2002
We reserve the right to change prices and terms any time.

Phone: Order Entry, 1-800-325-9167
For Information

To: Rick Remley
Copy: Dennis Shanks

Phil Young
3434 Dallas Rd.
Rockford, IL 61109

1994 Spring Special

Effective Date: January 17, 1994 through June 17, 1994

Qualification Period: Distributor must purchase a minimum of 30 cases (mix and match) before February 25, 1994 to qualify.

Spring Special Pricing: Distributors who qualify for the Spring Special will receive 1994 Spring Special Pricing on all reorders regardless of order quantity through June 17, 1994.

Terms: Single distributor branches with orders of $25,000 or more or multi-branch distributors whose branches group orders of $50,000 or more (not less than $10,000 for any one branch) will receive the following terms:

Orders placed by January 28, 1994 —
2% February 10, net 90

Orders placed by February 18, 1994 —
1% March 10, net 60

Otherwise standard terms of net 30 will apply.

To Rick Kemsley

ANCHOR

Phil Young
3434 Dallas Rd.
Rockford, IL 61109

DISTRIBUTOR

PRODUCT INFORMATION	SPECIES	CODE	SIZE	CASE PACK &WEIGHT	PRICE	SUGGESTED DEALER
BIOLOGICALS						
KILLED VIRUS						
ELITE 4™ (5 ml dose) IBR-BVD-PI_3-BRSV vaccine.	Cattle	123-511 123-531	50 ml 250 ml	24/4lb 12/8lb	7.70 38.50	10.24 51.21
ELITE 4-HS™ (5 ml dose) IBR-BVD-PI_3-BRSV vaccine and *Haemophilus somnus*.	Cattle	123-611 123-631	50 ml 250 ml	24/4lb 12/8lb	9.70 48.50	12.90 64.51
ELITE 9™ (5 ml dose) IBR-BVD-PI_3-BRSV vaccine and 5-way Lepto bacterin.	Cattle	126-011 126-031	50 ml 250 ml	24/4 lb 12/8 lb	8.70 43.50	11.57 57.86
ELITE 9-HS™ (5 ml dose) IBR-BVD-PI_3-BRSV vaccine, 5-way Lepto and *Haemophilus somnus* bacterins.	Cattle	123-411 123-431	50 ml 250 ml	24/4 lb 12/8 lb	11.70 58.50	15.56 77.81
BAR-4™ (5 ml dose) IBR-PI_3 vaccine and *Pasteurella haemolytica - multocida* mixed bacterin.	Cattle	113-911 113-931	50 ml 250 ml	24/4 lb 12/8 lb	4.50 21.00	5.99 27.93
BAR-4/SOMNUS™ (5 ml dose) IBR-PI_3 vaccine and *Pasteurella haemolytica, P. multocida* and *H. somnus* mixed bacterins.	Cattle	117-911 117-931	50 ml 250 ml	24/4 lb 12/8 lb	7.50 37.00	9.98 41.21
BRSV-KV (2 ml dose). Bovine respiratory syncytial virus.	Cattle	124-011 124-021	20 ml 100 ml	24/4 lb 12/4 lb	3.60 18.00	4.79 23.94
MODIFIED LIVE VIRUS						
IBR-BVD-PI_3 (2 ml dose) IBR-BVD-PI_3 vaccine.	Cattle	110-251 110-221	20 ml 100 ml	24/5 lb 12/9 lb	2.60 8.50	3.46 11.31
IBR-PI_3/BAR SOMNUS 2P™ (2 ml dose) IBR-PI_3 vaccine and *H. somnus, P. haemolytica - multocida* mixed bacterins.	Cattle	119-411 119-431	20 ml 100 ml	24/5 lb 12/7 lb	3.50 15.00	4.66 19.95

10 RNF Remedy

Phil Young
3434 Dallas Rd.
Rockford IL 61109

ANCHOR

DISTRIBUTOR

PRODUCT INFORMATION	SPECIES	CODE	SIZE	CASE PACK &WEIGHT	PRICE	SUGGESTED DEALER
IBR-BVD-PI$_3$/BAR SOMNUS 2P™ (2 ml dose) IBR-BVD-PI$_3$ vaccine and *H. somnus*, *P. haemolytica - multocida* mixed bacterins.	Cattle	119-321 119-331	20 ml 100 ml	24/5 lb 12/7 lb	3.80 17.00	5.05 22.61
CLOSTRIDIALS						
NEW! **Alpha-7™** (2 ml dose) *Clostridium chauvoei, septicum, novyi, sordellii, perfringens* Types C&D bacterin-toxoid.	Cattle	113-511 113-531 113-551	20 ml 100 ml 500 ml	24/2 lb 12/4 lb 6/8 lb	Sales Agent Agreement	Sales Agent Agreement
BAR-VAC®-7/SOMNUS (5 ml dose) *Clostridium chauvoei, septicum, novyi, sordellii, perfringens* Types C&D bacterin-toxoid and *Haemophilus somnus*.	Cattle	118-711 118-721 118-731	50 ml 250 ml 1000 ml	24/4 lb 12/8 lb 6/17 lb	4.40 21.50 84.00	5.85 28.60 111.72
BAR-VAC®-7/PINKEYE (5 ml dose) *Clostridium chauvoei, septicum, novyi, sordellii, perfringens* Types C&D bacterin-toxoid and *Moraxella bovis*.	Cattle	122-511 122-531	50 ml 250 ml	24/4 lb 12/8 lb	6.60 30.00	8.78 39.90
BAR-VAC® - CD/T (5 ml dose cattle) (2 ml dose sheep) *Clostridium perfringens* Types C&D and *Clostridium tetanus* toxoid.	Cattle Sheep	120-311 120-321	50 ml 250 ml	24/4 lb 12/8 lb	3.35 15.75	4.46 20.95
C-D TOXOID (5 ml dose cattle & swine) (2 ml dose sheep) *Clostridium perfringens* Types C&D toxoid.	Cattle Sheep Swine	110-911 110-921	50 ml 250 ml	24/4 lb 12/8 lb	1.50 5.50	2.00 7.32
REPRODUCTIVE						
VIBRIO-LEPTO-5™ (5 ml dose) *Campylobacter fetus* and 5-way Lepto mixed bacterin.	Cattle	117-611 117-621	50 ml 250 ml	24/4 lb 12/8 lb	2.90 13.00	3.86 17.29

To Rick Kennedy

Phil Young
3434 Dallas Rd.
Rockford, IL 61109

ANCHOR

DISTRIBUTOR

PRODUCT INFORMATION	SPECIES	CODE	SIZE	CASE PACK &WEIGHT	PRICE	SUGGESTED DEALER
VIBRIO-LEPTO-5/SOMNUS™ (5 ml dose) *Campylobacter fetus*, 5-way Lepto and *H. somnus* mixed bacterins.	Cattle	120-111 120-131	50 ml 250 ml	24/4 lb 12/8 lb	4.50 21.50	5.99 28.60
BAR SOMNUS/LEPTO-5™ (2 ml dose) *H. somnus* and 5-way Lepto.	Cattle	121-621 121-631	20 ml 100 ml	24/2 lb 12/4 lb	2.90 13.00	3.86 17.29
BREED-BACK 10™ (5 ml dose) IBR-BVD-PI_3 vaccine *Campylobacter fetus*, 5-way Lepto and *H. somnus* mixed bacterins.	Cattle	120-921 120-941	25 ml 100 ml	24/3 lb 12/7 lb	4.60 14.50	6.12 19.29
BACTERINS						
BAR SOMNUS™ (2 ml dose) *Haemophilus somnus* bacterin.	Cattle	115-011 115-021	20 ml 100 ml	24/2 lb 12/4 lb	1.60 7.00	2.13 9.31
BAR SOMNUS/2-P™ (2 ml dose) *Haemophilus somnus*, *P. haemolytica - multocida* mixed bacterins.	Cattle	115-611 115-621	20 ml 100 ml	24/2 lb 12/4 lb	1.95 9.00	2.59 11.97
LEPTO-5 (2 ml dose) 5-way Lepto bacterin.	Cattle Swine	118-431	100 ml	12/4 lb	5.25	6.98
SOMATO-STAPH® (5 ml dose) *Staphylococcus aureus* bacterin.	Cattle	104-121 104-131	50 ml 250 ml	24/4 lb 12/8 lb	5.60 26.00	7.32 34.58
SOMATO-STAPH®/LEPTO-5 (2 ml dose) *Staphylococcus aureus* and 5-way Lepto mixed bacterin.	Cattle	120-211 120-231	20 ml 100 ml	24/2 lb 12/4 lb	6.25 30.00	8.31 39.90
SERUMS						
BO-BAC-2X™ *E. coli*, *P. multocida*, *S. typhimurium*, *C. pyogenes* antiserum concentrate.	Cattle	113-721	250 ml	12/8 lb	16.89	22.46
BAR-GUARD-99™ (10 ml dose calves) (2 ml dose lambs) Oral *E. coli* antiserum.	Calves Lambs	108-111 108-121	10 ml 50 ml	12/2 lb 12/4 lb	3.45 16.10	4.59 21.41
C-D ANTITOXIN *Clostridium perfringens* Types C&D antitoxin.	Cattle Swine Sheep	101-821	250 ml	12/8 lb	14.90	19.82

10 Rick Kennedy

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DISTRIBUTOR

PRODUCT INFORMATION	SPECIES	CODE	SIZE	CASE PACK & WEIGHT	PRICE	SUGGESTED DEALER
SWINE						
ERY-MUNE C™ (2 ml dose) Erysipelas bacterin.	Swine	100-841 100-861	100 ml 250 ml	12/4 lb 12/8 lb	1.59 3.90	2.11 5.19
HYDROVAC™/AVE (2 ml dose) Live avirulent oral or injectable erysipelas bacterin.	Swine	112-811 112-821	20 ml 100 ml	24/2 lb 12/4 lb	2.80 5.30	3.72 7.05
TRUE-VAC-2™ (2 ml sow dose) (1 ml pig dose) *Bordetella bronchiseptica*, *P. multocida* Type D bacterin-toxoid.	Swine	123-111 123-131	20 ml 100 ml	24/2 lb 12/4 lb	2.17 9.66	2.89 12.85
COMPANION ANIMAL						
FELIN-L™ (.5 ml I.M. or S.Q., intranasal & intraocular) Feline distemper MLV vaccine.	Cat	118-831	0.5 ml w/syringe	96/8 lb (4x24x.5 ml)	2.03	2.94
FELIN-RC™ (.5 ml dose intranasal & intraocular) Feline distemper, rhinotracheitis, calici modified live virus vaccine.	Cat	118-941	25x0.5 ml	100/3 lb (4x25x.5 ml)	1.66	2.41
SOLO-JEC-7™ (1 ml dose I.M. or S.Q.) Distemper, hepatitis (CAV-1) (CAV-2), parainfluenza, parvovirus, *L. canicola-icterohaemorrhagiae*.	Dog	122-121	1 ml w/syringe	96/8 lb (4x24x1 ml)	1.54	2.23
		122-151	25x1 ml wo/syringe	100/3 lb (4x25x1 ml)	0.95	1.38
PHARMACEUTICALS						
BENFITAL™ A fiber-based nutritional supplement for young calves. A source of oral electrolytes and glucose.	Cattle	402-111 402-121 402-131	18x70gr 75x70 gr 1.8 kg	8x18/27lb 75/15 lb 4/19 lb	30.13 121.30 37.65	40.07 161.33 50.07
BLUE LOTION AEROSOL Topical antiseptic.	Multi	400-511	10 oz	12/10 lb (840/700 lb)	1.85	2.46
CHAPLESS TEAT DIP 2% Chlorhexidine Concentrate and glycerin. Makes 4 gallons	Cattle	345-731	Gallon	4/38 lb (108/1026 lb)	13.30	17.69
EPINEPHRINE For treatment of anaphylactic shock.	Multi	440-011	10 ml	12/1 lb	2.00	2.66

Beef Today®
MARCH 1991

WATCH WHERE YOU'RE SHOOTING!

Intramuscular injections are giving retailers fits

By NITA EFFERTZ

PHOTO: BILL MILLER

"STEAK CUTTERS WANT A SOLUTION NOW, not three months from now. If you don't need seven-way, don't use seven-way. If you do need it, don't put it in the muscle," says veterinarian Bob Bolander.

A half dozen years ago, the beef industry buried a problem that has come back to haunt it. To rid cattle of unsightly surface knots from clostridial vaccines, cattlemen put the shot in the muscle instead. Out of sight, out of mind. But not so in the eyes of beef customers.

Today, 12% to 15% of beef primals have some type of injection-site lesion that must be trimmed away. Retailers and steak cutters are angry. Some chains have threatened to boycott top sirloins from certain regions of the country. It is all that others can do to keep their employees from making a media issue of the problem. They say their concerns are twofold: the safety and wholesomeness of the beef first, and the economic loss associated with product and manpower waste second.

Although beef-industry leaders insist the problem is one of "quality control," they acknowledge that it could become a food-safety issue if not remedied quickly. The lesions have been described as abscesses. What's more, USDA's own meat inspectors have been known to send samples of damaged injection-site tissue to pathology marked "suspect cancer lesion."

"The concern is that these lesions will be perceived as something other than what they are, which is sterile scar tissue in the muscle," says Mike Bowles, a Texas feedlot manager and chairman of NCA's Beef Quality Assurance Task Force. "We know what we're dealing with, but what would a consumer think if he cut into a steak and found scarified tissue? That it is tainted."

"This situation of tissue damage has gotten completely out of hand the last couple of months," one retail meat supervisor told the NCA task force. "We've seen employees threaten to go to the media with the issue. Our people are concerned about the food-safety aspect of beef with damaged tissue."

The problem is being caught before it hits the meat case or dinner plate, but just barely. Most lesions are buried too deep to be discovered at the packing house.

An ongoing checkoff-funded study found that seven-way shots given 60 days before slaughter caused injection-site lesions 88% of the time. But fewer than 7% of those in the round and none of those in the top sirloin could be detected on the kill floor. Packers estimate they trim just 6% of carcasses for injection-site lesions—far below the incidence rate on primals when retailers and steak cutters were surveyed.

Steak outlets say the lesions in many cases force them to waste the entire product, since trimming the sirloin to make smaller steaks won't fit their menu constraints. And retail meat buyers report losing four to six man-hours a week just to sanitize equipment they say has been contaminated by abscesses.

So what's the fix? The NCA task force came up with both short- and long-term solutions after a recent meeting with veterinary leaders and vaccine manufacturers. Thanks to rapid-fire meetings in the Central Plains this winter, much of the feedlot industry has already gotten this message:

1. Immediately stop all intramuscular injections of clostridial bacterins in favor of a subcutaneous shot in the neck region—preferably "tenting" the skin to prevent hitting muscle tissue.

2. Discourage the use of repeat or multiple clostridial injections, especially late in the feeding period.

3. Avoid intramuscular injections of

all animal-health products whenever another route of administration has been approved on the label.

The task force says it has reached managers of more than 10 million fed cattle. It also believes a goal of eliminating 90% of the preventable lesions by the end of this year and 95% by the end of 1992 is attainable if cattlemen comply with the recommendations.

"We think we can address 70% of the problem at the feedlot level. The rest will depend on backgrounders and cow-calf producers," says North Platte, Neb., veterinarian Bob Bolander. He notes that injections given in the muscle at weaning or even branding can still cause lesions that must be trimmed months later.

Billbacks—when a buyer bills the cost of product defects back to the seller—are another reason to take injection-site lesions seriously. "Most packers have done some billback for this problem because they are facing it from their customers," says Bolander. "We think of it as a feedlot problem now, but the cow-calf segment certainly isn't immune from it."

He cites a Nebraska producer who had 100 head custom-fed and received a $189 billback from the packer. "The feedlot crew correctly gave the seven-way in the left neck and viral antigens in the left rump, and so assumed the billback was for bruising," notes Bolander. "But when the same 100 head received a $3,000 billback from the fabrication facility, the feedlot investigated and found it was due to injection-site lesions on the inside round of the right leg. That was a shot given at branding time."

Don't be surprised if billbacks increase in the near term—lesions will be far more visible in the neck. The NCA task force hopes that most lesions from proper "sub-Q" injections will peel with the hide on the kill floor. "But in the short run, if all those shots go into the neck there will be more trim there. I'd assume the packer isn't going to take the full hit," Bowles says.

Feedlot consultant Jim Sears, Bridgeport, Neb., says the risk of injury makes him skeptical of tenting sub-Q neck injections. "Moving the seven-way to the neck isn't a problem—our lots have done that for some time now," he says. "But tenting isn't practical. We're continuing to use a one-handed technique using a short needle at a sharp angle. You do the best you can to stay out of the muscle, but even a sub-Q injection will cause some lesion simply because of the antigen."

Many feedlot managers have opted to reduce their use of seven-way clostridial bacterins. "We haven't been boostering with them for some time," Sears says. "Some of our yards don't give any clostridials on heavier incoming cattle. Frankly, we've had some difficulty showing an economic benefit for the product on yearling cattle."

Because seven-way is a relatively cheap vaccine, it found routine use in many feedlots, especially late in the feeding period. Then it was thought to reduce overeating and sudden death cases. "We used to reason that since it can't hurt and might help, why not use it," Sears says. "But I think the potential for billbacks and damage to beef's image should make feeders think twice."

"This situation of tissue damage has gotten completely out of hand the last couple of months. We've seen employees threaten to go to the media with the issue. Our people are concerned about the food-safety aspect of beef with damaged tissue"

Clostridials are the main, but not the only, culprit causing injection-site lesions. Some common antibiotics have been shown to cause similar lesions, though not as severe. But unlike clostridials, which work equally well intramuscularly or subcutaneously, antibiotics are often labeled "I.M." because of efficacy. Although the task force would like to see intramuscular use of antibiotics minimized, it realizes that producers have fewer options here.

Sears agrees. "There's a limited number of antibiotic products available, and only some of them can be given intravenously or sub-Q. It's a trade-off between what might be ideal from a carcass standpoint and what is practical at the production level."

Although his crews try to spread out antibiotic injections, limit the use of certain products, and go intravenously late in feeding, Sears admits, "We aren't totally avoiding the hip area. Because of the high volume of many antibiotic injections, it's pretty difficult to put all that material in the neck, and it can produce enough soreness to diminish the response."

Fortunately, use of injectable antibiotics is normally case by case. "Unlike seven-way, which tends to be a whole-pen kind of treatment, you're not going to mass medicate with an injectable antibiotic simply because one calf has a snotty nose," says NCA science and technology specialist Gary Cowman. "Our study looked at lesions produced 30 and 60 days before slaughter. In the practical world, we don't often treat with injectable antibiotics that late."

Still, rationalizing any lesions isn't something the industry will do long term. The NCA task force made it clear to animal-health companies that they expect current and future products to be backed up with tissue reaction studies as soon as possible. Says Bowles: "I don't want to have to wonder whether something I'm using might have side effects I wasn't told about."

But he and others on the task force also compliment the companies for their willingness to address the problem. All the companies that make a seven-way clostridial are in the process of changing labels to request sub-Q use only. Most are investigating other sites and methods of administration for injectable intramusculars. And genetically engineered products promise vaccines with fewer contaminants and possibly irritating adjuvants.

In the meantime, feedlot advisers like Sears await tissue reaction studies on current products. "With antibiotics, I think it's a mistake to condemn all intramuscular use. Certain products may cause little or no problem if you allow a certain healing time," he says. "The point is, we need tissue studies so we know what we're using." ◀

New Product Intro

Help in Injection Site Blemishes Arrives

By Steve Dittmer
Publisher

Some things just aren't like they used to be.

Sometimes, that's fine, even if it feels a little strange.

A news conference unlike any this reporter has ever attended was held in Denver as an adjunct to the NCA's midyear meeting. It was a new product introduction news conference — and company personnel weren't even at the speakers' table. They hardly said a word. Why?

Because the issue management philosophy of industry groups like the NCA often now requires much closer cooperation between the companies who supply goods and services and cattlemen's associations, in order to provide the tools cattlemen need in time to fix problems.

Two years ago, the NCA launched a determined effort to study a newly recognized problem — injection site defects in the carcass, and the resulting dollar loss of packer cut-outs. With data collected through an intensive beef quality audit, the NCA in 1990 issued a challenge to animal health companies to come up with a solution to the problem in the form of new and less reactive vaccines.

Working closely with the NCA, Miles Agriculture Division (formerly Mobay, formerly Cutter) first developed supporting data to substantiate the efficacy of administering their clostridial vaccines Sub-Q (subcutaneously) in addition to IM (intramuscularly). Sub-Q administration, particularly via the "tented" technique, was a first important step in addressing injection site reactivity.

The next step was developing a completely new vaccine, designed to be administered in a 2 ml. dose, compared to the customary dosage of 5 ml. This new clostridial, "Vision," has proven to be both efficacious at 2 ml. and less reactive. Miles feels Vision vaccine is a major advancement toward the industry goal of producing highest quality, wholesome beef.

To underline the gravity of the injection site problem, as well as the importance of the availability of the new vaccine to combat it, a who's who in beef quality assurance spoke at the news conference. NCA Beef Quality Assurance Task Force members who spoke included Jack Algeo, Cal Poly, San Luis Obispo, Ca.; Mike Bowles, chairman, Amarillo; James Furman DVM, Alliance, Ne.; Bob Bohlender DVM, North Platte, Ne. and Wes Bonner DVM, Veribest Cattle Feeders, Veribest, Tx. Gary Smith, Ph.D., Colorado State University and National Beef Quality Audit chairman also spoke.

"Being involved in the start-up of the injection site study, I am particularly aware of the importance of this product," Bohlender said. "It is a tremendous credit to the NCA, Beef Board support and the biological manufacturing industry to have this product available. Only two years time after identifying and quantifying this problem, we have a bottle in our hand.

"I'm a practicing veterinarian and work with a lot of commercial cow/calf operations. Many of these are large ranches and a high percentage of them retain ownership. I also work with some stocker/yearling operations and large feedlots, especially with their arrival programs.

"We have had a lot of problems with 5 ml. 7-way. All brand name 7-way products cause the problem. When used intramuscularly, we know lesions will still be present at slaughter. In one instance in Nebraska, 7-way, administered in the right hind leg at branding time, caused a $30 per head trim and billback to the feedlot."

Bohlender continued: "Over the last few years, we have seen some feeders experience loss from clostridial diseases when they quit some vaccinations to avoid lesions.

Jim Furman, DVM

"I field-tested this new 2 ml. vaccine in seven different herds. We selected herds that had a history of a lot of 7-way vaccine problems (with 2 ml. dose administered).

"I was very satisfied with the results of the field tests of the 2 ml. vaccine and will recommend its use by all of my clients. The clients who cooperated with the study were also very happy with the results. They are anxious to use it on their calves and cows," Bohlender continued.

"I've been asked to speak to you about a problem in feedlot cattle that I saw approximately two years ago," Jim Furman said. "I started seeing some lumps from an injection site on some of the cattle at the feedyards I was working with.

"Most of these lumps seemed to resolve themselves at the feedyard prior to the animals being shipped to the packing plant for slaughter. However, one day I was asked to go to the packing plant to inspect some of the carcasses that had been slaugh-

Left to right, Mike Bowles, Wes Bonner and Jack Algeo.

tered that day from our feedyard. Many of the carcasses at that packing plant had been trimmed up over the chuck area to the tune of anywhere from one-quarter lb. to 3 lbs. This is the area we had been giving the usual 7-way clostridial vaccination at processing time, and again at revaccination or implant time.

"At the time I was of the belief that we had some contamination in our processing technique, either in our equipment or in the bottles of vaccine we were using as a supply reservoir for these injections.

"It was at that time the feedyard manager decided, in order to get rid of these injection site defects, we had to do something drastic. We discontinued the use of 7-way clostridial vaccinations on our heavy cattle.

"It was not until some time later, when we continued to send cattle to the same packing plant with the same carcass blemishes from the clostridial vaccine, that we found the packer was starting to bill back our feedyards and ultimately the client who owned these cattle to the tune of $5 to $7 to $8 per head going through the slaughter plant.

"This set the management off drastically, and they asked me point-blank 'How soon are we going to be done with this problem? How soon can you quit using that vaccine? How soon can you stop this costly problem in the cattle we're feeding?'

"My answer had to be probably four, five, maybe six months. See, all of the cattle in that feedyard had been handled and processed in exactly the same manner, so...it was another six to seven months before we shipped the last lot of cattle."

Now granted, not every animal had a problem, Furman said. But the chain at the packing plant was moving at 300+ head per hour. It was obvious to him in many visits to the plant that in order to ensure complete eradication of the blemish from the carcass, they were taking in excess of 2 lbs. at most every injection site.

"Well, needless to say, this made an awful big impression on me," Furman said. "And from that time on, we have not used any 7-way clostridial vaccine on cattle that are under 150 days from slaughter.

"It was just in January of 1992 that I was approached by the Miles people to field-study a new 2 ml. 8-way clostridial vaccine in some of the cattle in the feedyards I work with. I took two pens of cattle, one being 205 head of steers on February 3rd, and injected them two-handedly with the tented subcutaneous technique on the right side of the neck with 2 ml. of Vision vaccine. On February 7th, I injected another lot of cattle, 95 head, in the same site, again with the two-handed tented subcutaneous technique.

"The first set of cattle, 205 head, were hand palpated on the neck. On this 205 head, 11 days post injection, I found 60 percent that had kind of a raised weal, 1 1/2" in diameter. I found another 25 percent to have a palpable lesion less than an inch in diameter around the injection site. I found another 15 percent of these had no lesion that was palpable at all.

"Of the second group of cattle, 95 head that were just seven days post-vaccination , 90 percent had a 1 1/2" raised injection lesion at that time and the other ten percent had no lesions at all," Furman said.

"Upon observing these cattle in the pens prior to putting them in the chute, there were three head, or one percent, I could see from a distance that had raised lesions due to that injection. None of these calves were painful at the injection site and none of them had abscesses or required any treatment whatsoever due to the injections."

The feedyard owner Furman was working with stated, "If we hadn't put them in this alley and palpated them, we wouldn't have been aware of any reaction taking place except for the three head visible in the pen, and we had to look for them."

"He, ncr I, have any problems with the reduced 2 ml. dose," Furman said.

Approximately 100 days later, on May 27, 1992, Furman followed the 205 head of cattle to the Excel Packing Plant at Fort Morgan, Co. and observed them clear to the cooler. Not one animal of the 205 head receiving the new 2 ml. Vision vaccine had any injection site trim on the neck area where the 2 ml. dose was given.

Furman thanked the NCA for initiating this project. He also thanked Miles for "working with the cattle industry in ways I've never seen before in developing what cattlemen need."

Vision protects cattle against blackleg and other clostridial cattle diseases. The vaccine is available in familiar 4-way, 7-way and 8-way combinations. The reduced dose product has been tested extensively in field trials. Histological studies indicate the dollar loss from carcass defect cut-outs will be significantly reduced when the less reactive 2 ml. vaccine is used.

(Continued on page 49)

Help in Injection Site Blemishes Arrives

(Continued from page 43)

New Vision is not merely a reduced volume of a normal 2 ml. product. It is a new vaccine, made possible because of unique, patented, Spur (R) adjuvant and the innovative APS (TM) Antigen Purge System (TM).

Spur adjuvant long has been recognized as a superior adjuvant. Vastly multiplied "attachment sites," plus the ability to entrap antigen in the matrix of the molecule, prevents settling out as is common with aluminum hydroxide adjuvants. The entrapment feature also serves to protect the antigen from being destroyed as quickly by white blood cells, giving the vaccine a longer period to build immunity.

"Ten to twelve years ago, we asked biological manufacturers to give us an intramuscular bacterin for ease of administration," Wes Bonner said. "They responded to our request with efficacious products. Since we are now more attuned to *beef* rather than just *cattle*, we may have made a mistake back then. I am not the only feedlot manager that had received negative feedback and charge-backs from packers due to injection site lesions and scars. And, I am not the only veterinarian to be able to trace back some of these complaints to biologicals.

"We must use biologicals to protect the animals in our care. We must reduce the incidence of carcass blemishes that increase trim loss. The answer appears to be in the direction of using efficacious biologicals with a much lower tissue reaction, so carcass lesions are minimized.

"Our beef customers not only want a quality product when they purchase beef, at our prices they deserve it."

Anti-clostridial product reduces carcass defects

■ By ROD SMITH
Feedstuffs Staff Editor

DENVER, COLO. — The agricultural division of Miles, Inc., has introduced a clostridial vaccine that cattle industry leaders called "user friendly" and said it addresses a kind of Catch-22 situation.

The vaccine, Vision, allows cattle feeders to vaccinate against clostridial problems while eliminating or reducing significantly "knots" and lesions and improving overall quality.

Its use will increase the value of cattle to ranchers and yards by decreasing losses for carcass defects and increasing beef's competitiveness, industry people said.

The vaccine was rolled out during a news conference at the National Cattlemen's Assn. (NCA) mid-year meeting here.

In speaking to the conference, Mike Bowles, a cattle industry management and marketing consultant from Amarillo, Texas, and chairman of NCA's beef quality and safety asssurance task force, explained that the industry's beef quality audit identified a number of problems in cattle production that cause cattlemen to lose almost $280 per head on every head of fed cattle marketed.

He noted that lesions or scars in the muscular tissue are one of those problems, and he said that these defects were traced to damage caused during intramuscular injection of pharmaceutical products (injection-site defects). He said that the defects could be corrected partly through education efforts, which did overcome a lot of the problem.

Dr. Gary Smith, a meat science specialist and holder of the Monfort Chair at Colorado State University in Ft. Collins, Colo., said that an educational effort reduced defect losses more than 40% in 18 months.

However, Bowles and Smith, who conducted the quality audit, emphasized that even the most skilled administration of pharmaceutical products could not completely resolve the problem, and, in fact, led to another problem that was outlined by Dr. Gary Cowman in a memo released at the meeting.

Cowman, director of the beef quality assurance program for the NCA, said that "the most prevalent cause (of injection-site defects) seemed to be commercial brands of clostridial 7-way products."

One solution, he said, was to move injection from intra-muscular to subcutaneous sites, which did reduce lesions significantly, but he said that feedlots found subcutaneous injection produced knots beneath the skin, i.e., a hard, raised swelling that was often 2-3 in. in diameter.

Cowman said that the knots normally diminish in size or disappear during the feeding period and are not a health or quality concern. However, he said that when they persist, they remain as hardened tissue in the hide, and packers tend to discount cattle for knots.

The Catch-22 predicament, Cowman said, is that the cattle feeder either loses money because of intra-muscular injection site defects or because of knots produced by the alternative to intramuscular procedures.

Dr. Bob Bohlender, a practicing veterinarian from North Platte, Neb., and past chairman of NCA's quality assurance task force, agreed and said that feeders, if they are discounted for knots, will opt back to intramuscular injections.

Consequently, Bowles said that the industry, through the NCA, "asked the animal health industry to develop a new generation of products to enhance herd health ... and improve quality and safety."

Vision is built to be administered in 2-ml doses rather than the normal 5-ml and is, therefore less reactive, Miles said.

Miles said that Vision is not a reduced volume of a normal 5-ml product but "a new vaccine" that's made possible through a combination of the Spur adjuvant and APS Antigen Purge System, which protects and ultrafilters the antigen to enhance the antigen's efficacy and give the vaccine a longer period to build immunity. ■

A KNOTTY ISSUE

Don't let a buyer back off because of injection-site blemishes

If your buyer threatens to discount or asks you to sort off calves with injection knots on the neck, Gary Cowman wants to hear about it. Go ahead, call him at 303-694-0305. Cowman is the staff coordinator for the Beef Quality Assurance (BQA) task force. NCA appointed the task force two years ago after packers, retailers and restaurant suppliers complained about injection-site lesions in the top round.

The magnitude of the problem became known in March 1991 when a survey found a 22.3% incidence of injection-site lesions—14.2% of which were active, fluid-filled lesions. The task force, which includes producers, veterinarians and representatives of the pharmaceutical industry, identified the major culprits as clostridial bacterins.

Many of the products in this class were originally labeled for subcutaneous use. But after users complained about unsightly knots, manufacturers responded with an intramuscular clearance, and the industry buried its problem in its customers' product.

The task force launched a campaign to clean up injection-site lesions by urging cattle feeders and producers to give all clostridial injections sub-Q rather than intramuscularly. Although the industry fell short of the task force's goal of eliminating 90% of preventable lesions by the end of 1991, it has made notable progress. As of July 1992, the incidence of injection-site blemishes was 12.1%, and surveys conducted periodically since last November have found no fluid-filled lesions.

The problem of hard, fibrous lesions remains partly because of antibiotic injections that must be given intramuscularly. What's more, though the task force's recommendations have been well circulated throughout the feedlot industry, many cow-calf producers are just now getting the message to keep clostridial injections (four-, seven- and eight-way) out of the muscle.

What worries Cowman and the rest of the task force is that producers who are doing their part to prevent injection-site lesions may face an unjust penalty in the marketplace. "We're hearing about more knots on the neck of calves because more of these shots are going subcutaneously where we'd like to have them," says Cowman.

He's also hearing from veterinarians—particularly in the Northern Plains—who say clients' calves are being discriminated against because of injection-site knots. "We've heard of order buyers asking producers to sort off the calves with noticeable knots," says Cowman. "Our position is that cattlemen shouldn't lose for doing things correctly. We asked them to do this, and we intend to support them."

To combat any attempt to discount calves with visible injection knots, the task force urges cattlemen to make these points known to their buyers:

1. Surface vaccine blemishes are not a defect to the hide, carcass or other salable product.
2. These blemishes do not affect the health and quality of the animal.
3. They indicate that the animal has been vaccinated and that the vaccination response has not been impeded.
4. As such, they should not be a point for pricing discounts.

"Discounting could have the exact opposite reaction than we want—causing producers to shift the injection site back to the deep muscle where the reaction will be more severe and cause significant product damage," says a statement issued by the task force.

> ***"Discounting could have the exact opposite reaction than we want—causing producers to shift the injection site back to the deep muscle where the reaction will be more severe and cause significant product damage"***—Beef Quality Assurance Task Force

The long-term solution to such knotty problems will involve better diagnosis to determine need, and also better products. A growing number of veterinarians believe that clostridial bacterins are overused—particularly late in the feeding period—because they're cheaply priced. The industry also needs better products, those that will be effective when given subcutaneously and those that will work with less irritating adjuvants.

Proving that the animal-health industry can respond in record time when challenged to do so, Miles Agricultural Division recently released a less reactive 2-ml clostridial vaccine available in four-, seven- and eight-way combinations. (The customary dose for a clostridial is 5 ml.)

Though Miles claims that its lower-dose product (called Vision) will significantly reduce injection-site reactions, the company still chose to label it for both intramuscular or subcutaneous use—and in that order. NCA's task force continues to recommend that all clostridial bacterins be given subcutaneously in the neck region using the "tented" technique.

Quality-conscious producers and feeders may get some help in complying with that recommendation in the near future. Reportedly under development now is a vaccine gun that would allow the user to "tent" the animal's skin with one hand, thereby eliminating the safety hazard associated with the two-handed "tenting" technique. In the meantime, don't lose Gary Cowman's number. ◀